Page 6 of 11

REMARKS/ARGUMENTS

The above-identified application has been reviewed in light of the Office Action mailed

on November 26, 2008. Claims 1-3, 5-14 are currently pending. By the present Amendment,

Applicant has amended independent Claim 1 and added new Claims 13 and 14 for consideration.

Claim 4 is cancelled herein. Applicant respectfully submits that the present Amendment does

not incorporate any new subject matter and is fully supported by the specification. In addition,

Applicant respectfully submits that Claims 1-3, 5-14 are allowable over the references of record.

In view of the amendments to independent Claim 1 effected herein and the following remarks

and arguments, Applicant respectfully requests favorable reconsideration and allowance of the

above-identified application.

The Office Action rejected Claims 1-2, 6-12 under 35 U.S.C. § 102(b) as being

anticipated by U.S. Patent No. 6,051,007 to Hogendijk ("Hogendijk"). Applicant respectfully

submits, however, that Hogendijk fails to disclose each and every element recited in Claims 1-2.

6-12 as presented herein.

Under 35 U.S.C. § 102(b), to anticipate a claim, a reference must disclose each and every

element set forth in the claim. (See MPEP 2131).

Independent claim 1 has been amended to recite, inter-alia, an apparatus for

approximating body vessels comprising: at least one fastener including a first fastener portion

having an anchoring leg portion and a second fastener portion having an anchoring leg portion

wherein at least one of the first fastener portion and the second fastener portion has a first

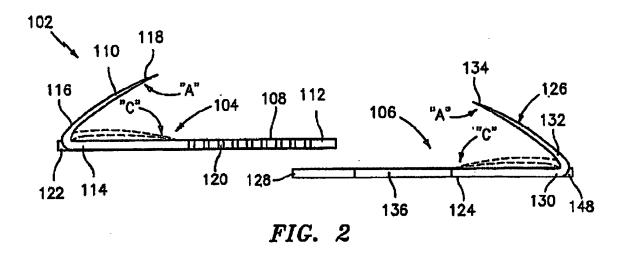
position in which the anchoring leg portion is adjacent the locking leg portion and a second

position in which the anchoring leg portion is spaced a distance from the locking leg portion.

6

Page 7 of 11

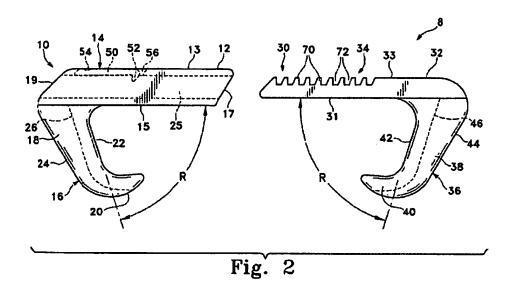
As described in the specification, for example on page 8, lines 3-7, anchoring leg portion 110 has a first position "A" in which sharpened proximal tip 118 is spaced a distance from locking leg portion 108 and can be collapsed to a second position "C" (as seen in phantom in FIG. 2 below) in which sharpened proximal tip 118 is in close proximity to locking leg portion 108.



In contrast, as illustrated in Fig. 2 below, Hogendijk relates to a sternal closure device 8 that includes a pair of opposed clamp members 10, 30. (See col. 4, lines 26-28). Clamp members 10, 30 each have elongate body portions 12, 32 integrally connected to or formed with engagement legs 16, 36. Engagement legs 16, 36 each include a spine portion 18, 38 having an inner sternal engagement surface 22, 42 for engaging and gripping about the sternal halves of a patient's severed sternum, as well as an outer surface 24, 44. (See col. 4, lines 36-44). Engagement surfaces 22, 42 are substantially straight but can also be curved in a general C-shaped configuration. Where spine portions 18, 38 have a substantially straight configuration, the spine portions 18, 38 are configured to extend at an angle "R" (most preferably about 75

Page 8 of 11

degrees) relative to body portions 12, 32 as shown in FIG. 2 below. This particular angular orientation between the respective body portions and spine ports is desirable to secure the sternal halves with the grasp of the clap members 10, 30 because, in the assembled state of the clamp members, and medial forces exerted on the sternum will cause the respective sternal halves to be urged upwards away from the foot portions 20, 40 and firmly within the grasp of clamp members 10, 30. (See col. 4, lines 58-67; see col. 5, lines 1-10).



Accordingly, Hogendijk does not disclose, *inter alia*, wherein at least one of the first fastener portion and the second fastener portion has a first position in which the anchoring leg portion is adjacent the locking leg portion and a second position in which the anchoring leg portion is spaced a distance from the locking leg portion. In fact, Hogendijk's engagement legs are positioned at a stationary angle "R", which, in its most preferred orientation is disposed at the single angle of 75 degrees. As such, the engagement legs are disposed in a single stationary

Response to Office Action Dated November 26, 2008

Application Serial No. 10/516,434 Amendment dated February 23, 2009 Docket: 2846 (203-3325 PCT US)

Page 9 of 11

position. In other words, the engagement legs of the Hogendijk device are not repositionable to

any second position.

For at least these reasons, Applicant submits that Claim 1 is patentable over Hogendijk

and is in condition for allowance. Furthermore, since Claims 2, 6-12 depend, either directly or

indirectly from Claim 1, it is respectfully submitted that Claims 2, 6-12 are at least patentable for

the reasons that independent Claim 1 is patentable. Accordingly, withdrawal of this rejection is

respectfully requested.

The Office Action rejected Claims 3 and 5 under 35 U.S.C. § 103(a) as being

unpatentable over Hogendijk. Claims 3 and 5 each depend from Claim 1. As such, for at least

the reasons discussed above with respect to Claim 1, Claims 3 and 5 add novel limitations that

are unobvious. As such, Claims 3 and 5 are in condition for allowance. Thus, withdrawal of this

rejection is respectfully requested.

Furthermore, new Claim 13 recites, inter alia, wherein at least one of the anchoring leg

portions of the first and second fastener portions includes a sharpened tip, wherein the sharpened

tip is configured and dimensioned to penetrate body vessels. New Claim 14 recites, inter alia.

wherein the sharpened tip is configured and dimensioned to affix the apparatus relative to the

body vessel.

As shown by Applicant in FIG. 2 above, and as recited in the claims, the sharpened tips

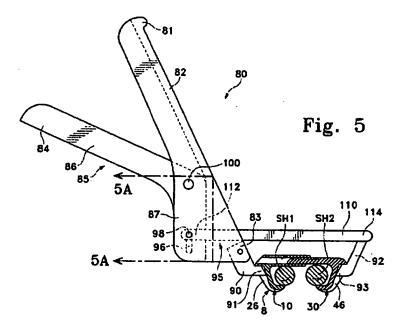
118. 134 provide a solution to a different problem than Hogendijk seeks to solve. In fact, the

sharpened tips 118, 134 of Applicant's device are used for penetration of the vessel. After

Page 10 of 11

penetration of the vessel, the anchoring leg portions 110, 126 of Applicant's device act as anchors to fix the location of the device relative to the vessel.

In contrast, and as shown below in FIG. 5, Hogendijk discloses foot portions 20, 40 (See FIG. 2 above) that are configured to be slightly spaced from the posterior surface of the sternum in the normal configuration of the assembly sternal closure device 8 about a reapproximated sternum. Foot portions 20, 40 are adapted to passively engage the posterior surface of the sternum in the event that the sternum tends to shift within the assembled sternal closure device 8 under the action of medial forces applied to the sternum. (See col. 4, lines 46-53).



Hogendijk's device essentially has engagement legs with atraumatic foot portions which have no design to penetrate and are not otherwise taught by Hogendijk to penetrate. Thus, Applicant provides a novel and unobvious solution to a different problem that Hogendijk does not seek to solve.

Response to Office Action Dated. November 26, 2008

Application Serial No. 10/516,434 Amendment dated February 23, 2009 Docket: 2846 (203-3325 PCT US)

Page 11 of 11

In view of the foregoing, it is respectfully submitted that all of the claims pending in the

application are in condition for allowance. With this in mind, reconsideration and allowance of

this application is respectfully requested.

Applicant believes that all issues raised in the Detailed Action have been responded to

fully. Should the Examiner believe that a telephone interview may facilitate resolution of any

outstanding issues, the Examiner is respectfully requested to telephone Applicant's undersigned

attorney at the number indicated below.

An early and favorable response on the merits is earnestly solicited.

Respectfully submitted,

Francesco Sardone

Reg. No.: 47,918

Attorney for Applicant(s)

Carter, DeLuca, Farrell & Schmidt, LLP 445 Broad Hollow Road - Suite 420

Melville, New York 11747 Tel.: (631) 501-5700

Fax: (631) 501-3526